June 3, 2019

Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
Submitted electronically at: https://www.federalregister.gov/documents/2019/03/04/2019-02224/21st-century-cures-act-interoperability-information-blocking-and-the-onc-health-it-certification

Attention: Public Comment on 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule

Office of the National Coordinator for Health IT:

Thank you for the opportunity to provide input on 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule. The Minnesota e-Health Initiative (Initiative) is pleased to submit comments as a public-private collaborative focused on advancing the adoption and use of electronic health records and other health information technology, including health information exchange. A legislatively authorized 25-member Advisory Committee guides the Initiative. Review Appendix A for list of members. The Minnesota Department of Health, Office of Health Information Technology, coordinates activities of the Initiative.

The Advisory Committee recognizes the need to implement certain provisions of the 21st Century Cures Act and align to the work of the Centers for Medicare and Medicaid Services. We want all partners to achieve interoperability and effectively use health information. Therefore, we recommend extending the timeframes to at least 18 months after the final rule to allow for sufficient effort and time for implementation.

Please consider the following comments and recommendations related to the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule. They are developed from input from across Minnesota and work of the Initiative. Contact Kari Guida, Senior Health Informatician, Office of Health Information Technology, Minnesota Department of Health at kari.guida@state.mn.use with any questions.

Sincerely,

Jennifer Fritz
Director, Office of Health Information Technology
Minnesota Department of Health

Alan Abramson, PhD
Advisory Committee Co-Chair
Minnesota e-Health Advisory Committee
Senior Vice President, IS&T and Chief Information Officer
HealthPartners Medical Group and Clinics

Sonja Short MD, FAAP, FACP
Advisory Committee Co-Chair
Minnesota e-Health Advisory Committee
Associate CMIO Ambulatory and Population Health
Fairview Health System

Comments and Recommendations

III. Deregulatory Actions from Previous Rulemaking	Page	Comments/Recommendations
Removal of Randomized Surveillance Requirements We propose to revise § 170.556(c) by changing the requirement that ONC– ACBs must conduct in-the-field, randomized surveillance to specify that ONC–ACBs may conduct in-the- field, randomized surveillance. We further propose to remove § 170.556(c)(2), which specifies that ONC–ACBs must conduct randomized surveillance for a minimum of 2% of certified health IT products per year.	7434	We support this revision to reduce administrative burden if randomized surveillance activity has produced no improvements towards health IT products.
Removal of the 2014 Edition From the Code of Federal Regulations We propose to remove the 2014 Edition from the Code of Federal Regulations (CFR).	7434-7435	To minimize confusion among developers and implementers of health IT, we support the removal of the 2014 Edition from the code of the federal regulations.
Removal of Certain 2015 Edition Certification Criteria and Standards We propose to remove the ONC Approved Accreditor (ONC–AA) from the Program ▪ remove the definition for ‘‘ONC Approved Accreditor or ONC–AA’’ found in § 170.502 ▪ remove processes related to ONC–AAs found in §§ 170.501(c), 170.503, and 170.504 regarding requests for ONC–AA status, ONC–AA ongoing responsibilities, and reconsideration for requests for ONC–AA status ▪ propose to remove the final rule titled ‘‘Permanent Certification Program for Health Information Technology; Revisions to ONC-Approved Accreditor Processes’’ (76 FR 72636) ▪ we propose its removal and § 170.575, which codified the final rule in the CFR ▪ we propose to revise the application process for ONC–ACB status in § 170.520(a)(3) to require documentation that confirms that the applicant has been accredited to ISO/ IEC 17065, with an appropriate scope, by any accreditation body that is a signatory to the Multilateral Recognition Arrangement (MLA)	7435	We recognize the need to reduce federal level administrative burden by removing the ONC–AA, and incorporating into an international body. It would be prudent to: ▪ analyze the effectiveness of the MLA with the IFA ▪ consider their processes for certification and how current members would be incorporated into that process (e.g., the peer evaluation for certification, etc.) ▪ compare IFA standards for exchange with current ONC standards, identify similarities, gaps, and what the costs would be to update to the IFA standards ▪ inform health IT developers and implementers of these details and ask for input toward this decision in the future

III. Deregulatory Actions from Previous Rulemaking	Page	Comments/Recommendations
with the International Accreditation Forum (IAF), in place of the ONC–AA accreditation documentation requirements ▪ requiring the ONC–AA to evaluate the conformance of ONC–ACBs to ISO/IEC 17065, we propose to revise § 170.523(a) to simply require ONC–ACBs to maintain accreditation in good standing to ISO/IEC 17065 for the Program		
Removal of Certain 2015 Edition Certification Criteria and Standards We propose the removal of certain certification criteria from the 2015 Edition that are included in the 2015 Edition Base EHR definition. The removal of these criteria would support burden and cost reductions for health IT developers and health care providers as noted above.	7435	We support the removal of most of the criteria from the 2015 Edition certification requirements, recognizing that these elements are important to clinical care and that they are part of USCDI standards for sharing, and that these standards will continue to evolve with the industry to better capture and share the information in a usable, standard and meaningful way. To that end, we also encourage the expanded use of USCDI standards for meaningful exchange and the availability of information for population health analysis to evaluate current public health programs, target interventions that support health equity, and identify future health issues before they become epidemics.
Removal of Certain 2015 Edition Certification Criteria and Standards: **Problem List** We propose to remove the 2015 Edition ‘‘problem list’’ certification criterion (§ 170.315(a)(6)).		We support the removal of the problem list.
Removal of Certain 2015 Edition Certification Criteria and Standards: Smoking Status We propose to remove the 2015 Edition ‘‘smoking status’’ criterion (§ 170.315(a)(11)), which would include removing it from the 2015 Edition Base EHR definition.	7436	We recommend not removing the smoking status from the 2015 Edition. This information is vital to local, state, and national work on reducing mortality and morbidity due to tobacco use and exposure.

III. Deregulatory Actions from Previous Rulemaking	Page	Comments/Recommendations
Removal of Certain 2015 Edition Certification Criteria and Standards: CCDS Summary Record—Create; and CCDS Summary Record—Receive We propose to remove these certification criteria from the 2015 Edition. (2015 Edition ''Common Clinical Data Set summary record— create'' (§ 170.315(b)(4)) and ''Common Clinical Data Set summary record— receive'' (§ 170.315(b)(5)) criteria that have not also been certified to the 2015 Edition ''transitions of care'' criterion (§ 170.315(b)(1)))	7437	We support removing the CCDA Summary of Care Create and Receive certification criteria as ONC proposes to keep the 2015 Edition 'transitions of care' criteria which includes the same functionality plus a direct-related transport functionality.
Removal of Certain ONC Health IT Certification Program Requirements We propose to remove certain mandatory disclosure requirements and a related attestation requirement under the Program. ▪ remove § 170.523(k)(1)(iii)(B), which requires health IT includes a detailed description of all known material information concerning limitations that a user may encounter in the course of implementing and using the certified health IT ▪ remove § 170.523(k)(1)(iv)(B) and (C) ▪ remove the Principle of Proper Conduct (PoPC) in § 170.523(k)(2)	7437	We recognize the purpose for removing this section in that the requirements are replaced by the Cures Act information blocking provisions. This seems reasonable only if there is a clear and usable process and authority for addressing specific concerns of information blocking.
Recognition of Food and Drug Administration Processes: Development of Similar Independent Program Processes—Request for Information We request comment on whether ONC should establish new regulatory processes tailored towards recognizing the unique characteristics of health IT (e.g., EHR software) by looking first at the health IT developer, rather than primarily at the health IT presented for certification, as is currently done under the Program.	7439	We support a process whereby the FDA is evaluating the health IT developer first and then other agencies (e.g., ONC) look at individual products of that developer. There have been many instances where the products have been sold to other developers and it has been difficult to identify if the product quality will be maintained, used and monitored through processes of the second (owner) developer in the same way. This is also an encouraging example of federal programs working together to help users of the health IT trust the products they have purchased.

IV. Updates to the 2015 Edition Certification Criteria	Page	Comments/Recommendations
USCDI 2015 Edition Certification Criteria We propose to adopt the USCDI Version 1 (USCDI v1) in § 170.213.	7441	We support the adoption of USCDI Version 1 with the following comments. We recommend adding gender identity and sexual orientation to the USCDI. This information is necessary to meet individual, community, and public health needs. We recommend clarifying medication prescribed vs. medication dispensed. We recommend analyzing the USCDI V 1 with what is needed by skilled nursing facilities for the October 1, 2019 implementation of the Patient Driven Payment Model and identify strategies to fill any gaps in future version of USCDI.
USCDI Standard—Data Classes Included: Pediatric Vital Signs The USCDI v1 includes the pediatric vital sign data elements, which are specified as optional health information in the 2015 Edition CCDS definition. Pediatric vital signs include: Head occipital-frontal circumference for children less than 3 years of age, BMI percentile per age and sex for youth 2– 20 years of age, weight for age per length and sex for children less than 3 years of age, and the reference range/scale or growth curve, as appropriate.	7442	We support the inclusion of pediatric vital signs. We recognize that not all settings would need this information but the information is significant enough to clinical, public, and population health to be required.
USCDI Standard—Data Classes Included: Clinical Notes The USCDI v1 includes a new data class, titled ''clinical notes.'' ''Clinical notes'' is included in the USCDI v1 based on significant feedback from the industry since the 2015 Edition final rule.	7442	We support the addition of clinical notes.
USCDI Standard—Data Classes Included: Provenance The USCDI v1 also includes a new data class, titled ''provenance.''	7442	We support the addition of provenance. We ask for clarity on how "author" works when numerous members of the care team write the notes. Is the author the final author or everyone who touched the notes?

IV. Updates to the 2015 Edition Certification Criteria	Page	Comments/Recommendations
USCDI Standard—Data Classes Included: Unique Device Identifier(s) for a Patient's Implantable Device(s) We request comment on whether we should add this UDI IG as a requirement for health IT to adopt in order to meet the requirements for UDI USCDI Data Class.	7443	We support the addition of UDI as it is important for patient safety, reducing administrative burden and opportunities to improve patient care.
USCDI Standard—Data Classes Included: Medication Data Request for Comment The USCDI v1 ''Medication'' data class includes two constituent data elements within it: Medications and Medication Allergies. With respect to the latter, Medication Allergies, we request comment on an alternative approach. This alternative would result in removing the Medication Allergies data element from the Medication data class and creating a new data class titled, ''Substance Reactions,'' which would be meant to be inclusive of ''Medication Allergies.'' The new ''Substance Reactions'' data class would include the following data elements: ''Substance'' and ''Reaction,'' and include SNOMED CT as an additional applicable standard for non-medication substances.	7443	We support substance and reaction as it can better identify and support medication treatment options for individuals. For example, the associated reaction can help to identify if there is a true allergy or if it could have been misinterpreted as an allergy and needs further testing if a patient's current conditions could be improved with the use of the potential allergen. Sharing this information could reduce the number of adverse events, and improve accurate clinical use of allergen substances.
Electronic Health Information Export For both use cases supported by this criterion, EHI export encompasses all the EHI that the health IT system produces and electronically manages for a patient or group of patients. This applies to the health IT's entire database, including but not limited to clinical, administrative, and claims/ billing data. It would also include any data that may be stored in separate data warehouses that the system has access to, can produce, and electronically manages		We applaud the inclusion of administrative and claims/billing data in the definition of EHI but seek clarity about how this will affect states' efforts and investments in administrative data uniformity, ACO and ACO-like organizations, and cost transparency.
Electronic Health Information Export We also propose the following metadata categories that would be excluded from this	7448	We agree with the proposed exclusions of metadata, as these types of information are not meaningful to an individual's health or health care.

IV. Updates to the 2015 Edition Certification Criteria	Page	Comments/Recommendations
criterion, and have listed examples for clarity below. We seek comment on these exclusion categories, and request feedback on what metadata elements should remain included for export, or be added to the list of data that would be allowed to be excluded in a subsequent final rule: ▪ Metadata present in internal databases used for physically storing the data. Examples include: Internal database table names, field names, schema, constraints, Triggers, Field size (number of bytes), Field type (String, integer, double, long), and Primary keys or object identifiers used internally for querying. ▪ Metadata that may not be necessary to interpret EHI export, including information that is typically required for processing of transactions such as encryption keys, internal user roles, ancillary information such as information stored in different formats, local codes for internal use; audit logs, record reviews, or history of change. ▪ Metadata that refers to data that is not present in the EHI export, such as links to files and other external attachments that are not part of the export, and information used in conjunction with data from other applications that is not part of the health IT.		Although all other types of individual EHI are of interest to the individual and their care givers, it is uncertain at this time how well each of those data elements will be able to be transported from one EHR to one individual's app or portal through an API. It is unclear what the use case or reason for the sharing of information between health systems in the discussion of exporting EHI of groups of individuals. The title of the section is Transitions Between Health IT Systems. This raises a few questions: ▪ Is this intended for a provider who sees patients at multiple locations and wants the information for their patients shared between systems? There is strong language in the document around 'provide a complete export of all EHI that is produced or managed by a health IT developer' to another health system, but no reason listed for sharing that information. ▪ Under what circumstances would an export (not expected to be real-time) for all available information on a group of individuals be suggested? ▪ Who could request this type of export? ▪ Who would need to authorize such an export, and for what purposes? ▪ Does each use case need prior consent by the individuals whose data would be exported? ▪ Under what circumstances would prior consent not be needed?
Electronic Health Information Export: **Timeframes** ONC seeks input on EHI export and timeframes. In particular, beyond exporting all the EHI the	7449	A health care provider requesting information on an individual should be able to set timeframes for EHI export. This might also apply to a researcher

IV. Updates to the 2015 Edition Certification Criteria	Page	Comments/Recommendations
health IT system produces and electronically manages, should this criterion include capabilities to permit health care providers to set timeframes for EHI export, such as only the ''past two years'' or ''past month'' of EHI?		requesting EHI export using a set timeframe, but only if each individual in the export has consented to sharing their information for that purpose.

V. Modifications to the ONC Health IT Certification Program	Page	Comments/Recommendations
Corrections ▪ Auditable Events and Tamper Resistance ▪ Amendments ▪ View, Download, and Transmit to 3rd Party ▪ Integrating Revised and New Certification Criteria Into the 2015 Edition Privacy and Security Certification Framework	7454	The corrections for these sections seem reasonable. It is helpful to have these attestations and testing to assure privacy and security based on HIPAA requirements. Due to Minnesota's Health Records Act consent requirements, additional attestation is currently required for Minnesota HIE service providers regarding consent.
Principles of Proper Conduct for ONC–ACBs ▪ Records Retention ▪ Conformance Methods for Certification Criteria ▪ ONC–ACBs To Accept Test Results From Any ONC–ATL in Good Standing ▪ Mandatory Disclosures and Certifications	7456	Records of certification for 'life of the editions' plus 3 years seems reasonable. We understand the use of conformance testing results where applicable instead of specific testing procedures when the conformance results show the same capabilities. We understand that Complete EHR certification is no longer an option in the 2015 CEHRT Edition, however would expect to see EHRs marketing themselves as HIE service providers to be certified in the Health IT Modules for HIE.

VI. Health IT for the Care Continuum	Page	Comments/Recommendations
Recommendations for the Voluntary Certification of Health IT for Use in Pediatric Care To support the first part of Section 4001(b) of the Cures Act, ONC considered the historical efforts on the Children's Model EHR Format, the input from stakeholders, and our own technical analysis and review of health IT capabilities and standards to develop a set of recommendations for voluntary certification for health IT for pediatric care. These include eight recommendations related to the Priority List: ▪ Recommendation 1: Use biometric specific norms for growth curves and support growth charts for children. ▪ Recommendation 2: Compute weight-based drug dosage. ▪ Recommendation 3: Ability to document all guardians and caregivers. ▪ Recommendation 4: Segmented access to information. ▪ Recommendation 5: Synchronize immunization histories with registries. ▪ Recommendation 6: Age- and weight-specific single-dose range checking. ▪ Recommendation 7: Transferrable access authority. ▪ Recommendation 8: Associate maternal health information and demographics with newborn. ▪ Recommendation 9: Track incomplete preventative care opportunities. ▪ Recommendation 10: Flag special health care needs.	7459	We support the Pediatric Care priority list. We recommend that the flag special health care needs align with and be a tool in public and population health activities as well as referrals. We see recommendation #8 as a powerful tool for addressing environmental health exposures. We suggest considering associating sibling, guardian, and father information and demographics for the purposes of identifying blood lead exposure and other environmental health exposures.
Health IT and Opioid Use Disorder Prevention and Treatment—Request for Information: **2015 Edition Certification Criteria** We seek public comment on how the existing 2015 Edition certification criteria as well as proposals within this proposed rule for revised or new criteria support OUD prevention and treatment.	7462	We recommend funds and resources to implement the following opioid and e-health recommendations. The Minnesota e-Health Initiative, in response to a request from Governor Dayton, developed a set of recommendations for using e-health to prevent and respond to opioid misuse

VI. Health IT for the Care Continuum	Page	Comments/Recommendations
		and overdose. These seven recommendations, attached as Appendix B, are highlighted below: • Provide resources to fully implement e-prescribing, with a focus on increasing the rate of e-prescribing controlled substances. • Improve prescription drug monitoring program to assure effective and seamless use of PDMPs by prescribers and dispensers thru the elimination of multiple log-ins. • Ensure that state and federal agencies, tribal governments, academia, local public health, payers, and other partners are able to appropriately access and analyze PDMP information for improved prevention, response, and care while safeguarding patient privacy in accordance law • Review, update, and provide education on e-health and opioids policies and guidelines to ensure dispensers, prescribers, payers, and other providers, including the care team 1) have appropriate and timely access to health information; 2) can subsequently share health information; and 3) understand their scope of action related to the health information. • Ensure access and coverage for all Minnesotans and providers, and provide resources for grants and technical assistance, to expand access to services and care enabled by telehealth, telemedicine and other forms of virtual technology to fill access gaps in opioid tapering and withdrawal, chemical dependency, mental health, and

VI. Health IT for the Care Continuum	Page	Comments/Recommendations
		alternative pain treatment and services. • Support state agencies and stakeholders in participating in statewide coordinated health information exchange services. State agencies include but are not limited to health, human services, corrections, education, and others as allowed by federal and state law. • Provide resources to public health to identify and address their information and information technology needs to prevent and respond to substance misuse and overdose. We recommend funding to improve and assure a strong electronic vital records system nationwide. There is a strong need to update and support the vital records systems across the country. Birth and death information is necessary for public health surveillance, identifying future health needs, and much more. The work and findings of the National Association for Public Health Statistics and Information Systems (NAPHSIS) and National Committee on Vital and Health Statistics (NCVHS) should guide this vital activity. We recommend funding for the electronic vital records system that would (1) expand broad scale, secure vital record systems implementation across jurisdictions, (2) support interoperable and intelligent real-time reporting of data from multiple sources, including electronic health records and medical examiner/coroner systems and (3) deliver rapid, seamless exchange of birth and death data with CDC and partners.

VI. Health IT for the Care Continuum	Page	Comments/Recommendations
Health IT and Opioid Use Disorder Prevention and Treatment—Request for Information: Revised or New 2015 Edition Certification Criteria in This Proposed Rule This proposed rule contains additional proposals to revise or add new criteria to the Program to better support care across the continuum. We believe these criteria and standards, highlighted below, can also support treatment and prevention of OUD. We seek comment specifically on the applicability of these criteria to the OUD use case. They are: ▪ USCDI ▪ Standardized API ▪ Electronic Prescribing and PDMPs	7462-7463	There is value in adding gender identity and sexual orientation to the USCDI as a strategy to better understand the opioid epidemic and communities affected.
Health IT and Opioid Use Disorder Prevention and Treatment—Request for Information: Emerging Standards and Innovations: Additional Comment Areas We further seek comment on effective approaches for the successful dissemination and adoption of standards including the NCPDP SCRIPT 2017071 standard (see section IV.B.2) that can support the exchange of PDMP data for integration into EHRs and also enable further adoption and use of Electronic Prescribing of Controlled Substances (EPCS).	7464	The Minnesota Legislature's position, as of today, is that PDMP data is available for view-only access to the state's database, so integration of data into the EHR is not allowed. In addition, the data collected by Minnesota's PDMP can be retained for only 12 months after January 1, 2020.
Health IT and Opioid Use Disorder Prevention and Treatment—Request for Information: Emerging Standards and Innovations: Additional Comment Areas We seek comment on a topic that involves health IT for both pediatric care and OUD prevention and treatment—Neonatal Abstinence Syndrome (or NAS).	7464-7465	We suggest working with NAPHSIS and NCVHS to better understand how vital records can be a tool or resource in surveillance of NAS.

VII. Condition and Maintenance of Certifications	Page	Comments/Recommendations
Assurances We also propose to establish more specific Conditions and Maintenance of Certification requirements for a health IT developer to provide assurances that it does not take any action that may inhibit the appropriate exchange, access, and use of EHI. These proposed requirements serve to provide further clarity under the Program as to how health IT developers can provide such broad assurances with more specific actions. ▪ Full Compliance and Unrestricted Implementation of Certification Criteria Capabilities: We propose, as a Condition of Certification, that a health IT developer must ensure that its health IT certified under the ONC Health IT Certification Program (Program) conforms to the full scope of the certification criteria to which its health IT is certified. ▪ Certification to the ''Electronic Health Information Export'' Criterion: We propose, as a Condition of Certification requirement, that a health IT developer that produces and electronically manages EHI must certify health IT to the 2015 Edition ''electronic health information export'' certification criterion in § 170.315(b)(10). ▪ Records and Information Retention: We propose that, as a Maintenance of Certification requirement, a health IT developer must, for a period of 10 years beginning from the date of certification, retain all records and information necessary that demonstrate initial and ongoing compliance with the requirements of the ONC Health IT Certification Program.	7465-7466	We support ONC's efforts to restrict information blocking. Regarding health IT developers, if there is a requirement, will the rule define who decides how the health IT developer is to participate in TEFCA? For example, can the developer/vendor decide, or should the client decide? Is it information blocking if the client is an HIE, but its vendor chooses not to connect to eHealth Exchange because as a vendor they choose to connect through Carequality and the HIE must choose a (willing) different vendor? Couldn't a health IT developer be connected in multiple ways depending their clients? How will these conflicts of interest be resolved?
Assurances: Trusted Exchange Framework and the Common Agreement—Request for Information ▪ We request comment as to whether certain health IT developers should be required to participate in the TEFCA as a means of providing assurances to their customers and ONC that they are not taking actions that constitute information blocking or any other action that may inhibit the appropriate exchange, access, and use of EHI. We would	7466-7465	Please see above.

VII. Condition and Maintenance of Certifications	Page	Comments/Recommendations
expect that such a requirement, if proposed in a subsequent rulemaking, would apply to health IT developers that have a Health IT Module(s) certified to any of the certification criteria in §§ 170.315(b)(1), (c)(1) and (c)(2), (e)(1), (f), and (g)(9) through (11); and provide services for connection to health information networks (HINs). These services could be routing EHI through a HIN or responding to requests for EHI from a HIN. ▪ In consideration of this request for comment, we welcome comment on the certification criteria we have identified as the basis for health IT developer participation in the Trusted Exchange Framework and adherence to the Common Agreement, other certification criteria that would serve as a basis for health IT developer participation in the Trusted Exchange Framework and adherence to the Common Agreement, and whether the current structure of the Trusted Exchange Framework and Common Agreement are conducive to health IT developer participation and in what manner.		
Communications Requirement	7468-7476	We see great value in more sharing on HIT. It provides providers across the care continuum the ability to talk about what is working and may therefore increase interoperability as providers find HIT that best fits their needs and settings.

VIII. Information Blocking	Page	Comments/Recommendations
Health Care Providers Definition The term ‘‘health care provider’’ is defined in section 3000(3) of the PHSA. We propose to adopt this definition for purposes of section 3022 of the PHSA when defining ‘‘health care provider’’ in § 171.102. We note that this definition is different from the definition of ‘‘health care provider’’ under the HIPAA Privacy and Security Rules. We are considering adjusting the information blocking definition of ‘‘health care provider’’ to cover all individuals and entities covered by the HIPAA ‘‘health care provider’’ definition. We seek comment on whether this approach would be justified, and commenters are encouraged to specify reasons why doing so might be necessary to ensure that the information blocking provision applies to all health care providers that might engage in information blocking.	7510	We request the final rule be explicit about the reach of this regulation and its effect on public health, including state and local health departments. We also request absolute clarity on the definition of “health care provider” so that there are no conflicts with privacy, security, and breach rules. We ask for clarity on conflicting definitions for providers that occur at the federal, state, and certified level.
Observational Health Information Although the information blocking provision applies to all EHI, we believe that information blocking concerns are especially pronounced when the conduct at issue has the potential to interfere with the access, exchange, or use of EHI that is created or maintained during the practice of medicine or the delivery of health care services to patients. We refer to such information in this section of the preamble collectively as ‘‘observational health information.’’ Such information includes, but is not limited to, health information about a patient that could be captured in a patient record within an EHR and other clinical information management systems; as well as information maintained in administrative and other IT systems when the information is clinically relevant, directly supports patient care, or facilitates the delivery of health care services to consumers.	7516-7517	The observational health information definition is important to information blocking regulation and the exceptions. We suggest providing more clarity and examples to assure full understanding and applicability of the definition.
Proposed Exceptions to the Information Blocking Provision: Preventing Harm We propose to establish an exception to the information blocking provision for practices that are reasonable and necessary to prevent harm to a patient or another person, provided certain conditions are met. Consistent with the definition of information blocking, we have identified certain risks to patient harm that arise in the context of access, exchange, or use of EHI. To qualify for this	7523-7525	We request guidance on how this exemption will be implemented with differences in state laws, who is allowed to get their own EOB, and implications for minors. It is necessary to assure there are no intended or unintended negative consequences on the

VIII. Information Blocking	Page	Comments/Recommendations
proposed exception, an actor's practice must respond to a risk that is cognizable under this exception. ▪ Risk of Corrupt or Inaccurate Data Being Recorded or Incorporated in a Patient's Electronic Health Record ▪ Risk of Misidentifying a Patient or Patient's Electronic Health Information ▪ Determination by a Licensed Health Care Professional That the Disclosure of EHI Is Reasonably Likely To Endanger Life or Physical Safety		health and well-being of teens, particularly our LGBTQ+ teens. We request the addition of mental health as a recognized harm. For example, providers must be able to prevent the release of labs that would indicate cancer, HIV or life-threatening disease to allow a provider to discuss directly with the patient.
Proposed Exceptions to the Information Blocking Provision: Promoting the Privacy of EHI We propose to establish an exception to the information blocking provision for practices that are reasonable and necessary to protect the privacy of an individual's EHI, provided certain conditions are met. Sub-exceptions: ▪ Precondition not satisfied ▪ Health IT developer of certified health IT not covered HIPAA ▪ Denial of an individual's request for their electronic protected health information in circumstances provided in 45 CFR 164.524(a)(1), (2), and (3) ▪ Respecting an individual's request not to share information	7526-7535	We recognize that this exception's precondition does include state's individual privacy and consent laws but more clarity is needed for actual implementation. Additional areas needing clarity include patients understanding what they have consented to and use of APIs and patients who receive care in a different jurisdiction in which they live (live in Wisconsin and seek care in Minnesota).
Proposed Exceptions to the Information Blocking Provision: Recovering Costs Reasonably Incurred: Costs Specially Excluded We propose that certain costs should be explicitly excluded from this exception regardless of the method for recovering the costs. We have proposed these excluded costs, which are detailed below, in an effort to provide additional clarity about the scope of this exception and to create guardrails for preventing potential misuse of the exception. ▪ Costs Due to Non-Standard Design or Implementation Choices ▪ Subjective or Speculative Costs ▪ Fee Prohibited by 45 CFR 164.524(c)(4) ▪ Individual Electronic Access	7540-7541	We ask for guidance/clarity on what is meant by individual electronic access and how this would apply in the exception.

VIII. Information Blocking	Page	Comments/Recommendations
▪ Export and Portability of EHI Maintained in EHR Systems		

X. Patient Matching Request for Information	Page	Comments/Recommendations
We specifically seek input on: It is a common misconception that technology alone can solve the problem of poor data quality, but even the most advanced, innovative technical approaches are unable to overcome data quality issues. Thus, we seek input on the potential effect that data collection standards may have on the quality of health data that is captured and stored and the impact that such standards may have on accurate patient matching. We also seek input on other solutions that may increase the likelihood of accurate data capture, including the implementation of technology that supports the verification and authentication of certain demographic data elements such as mailing address, as well as other efforts that support ongoing data quality improvement efforts.	7555	Most organizations engaging in HIE have well developed patient matching algorithms. Most have also independently created a standard for how name, address, and other demographic information is collected, and worked to train front-line staff for consistency across their health system. The difficulty is the lack of using the same standards across all providers in how this information is collected. We encourage the use of a national standard for how this information is collected to improve patient matching between health systems and other providers of care.

Appendices

Appendix A: Minnesota e-Health Advisory Committee 2018-2019

Members

Members

Alan Abramson, PhD, *Advisory Committee Co-Chair*, Senior Vice President, IS&T and Chief Information Officer, HealthPartners Medical Group and Clinics
Representing: Health System CIOs

Sonja Short, MD, *Advisory Committee Co-Chair*, Associate CMIO, Fairview Health Systems
Representing: Physicians

Sunny Ainley, Associate Dean, Center for Applied Learning, Normandale Community College
Representing: HIT Education and Training

Constantin Aliferis, MD, MS, PhD, FACMI, Chief Research Informatics Officer, University of Minnesota Academic Health Center
Representing: Academics and Clinical Research

Karl Anderson, Global Digital Health Senior Manager, Medtronic
Representing: Vendors

Laurie Beyer-Kropuenske, JD, Director, Community Services Division
Representing: Minnesota Department of Administration

Jennifer Fritz, MPH, Director, Office of Health Information Technology
Representing: Minnesota Department of Health

Cathy Gagne, RN, BSN, PHN, St. Paul-Ramsey Department of Public Health
Representing: Local Public Health

Mark Jurkovich, DDS, MBA, Dentist, Gateway North Family Dental
Representing: Dentists

Jennifer Lundblad, PhD, President and Chief Executive Officer, Stratis Health
Representing: Quality Improvement

Bobbie McAdam, Vice President, Information Technology, Medica
Representing: Health Plans

Jeyn Monkman, MA, BSN, NE-BC, Institute of Clinical Systems Improvement
Representing: Clinical Guideline Development

Lisa Moon, PhD, RN, CEO Advocate Consulting
Representing: Nurses

Heather Petermann, Division Director, Health Care Research & Quality, Minnesota Department of Human Services
Representing: Minnesota Department of Human Services

James Roeder, Vice President of IT, Lakewood Health System
Representing: Small and Critical Access Hospitals

Peter Schuna, Chief Executive Officer, Pathway Health Services
Representing: Long Term Care
Co-Chair: Health Information Exchange Task Force

Jonathan Shoemaker, Chief Information Officer, Allina Health
Representing: Large Hospitals

Steve Simenson, BPharm, FAPhA, President and Managing Partner Goodrich Pharmacy
Representing: Pharmacists

Adam Stone, Chief Privacy Officer, Secure Digital Solutions
Representing: Expert in HIT

Meyrick Vaz, Vice President - Strategic Market Partnerships, UnitedHealthcare Office of the CIO
Representing: Health Plans

Donna Watz, JD, Deputy General Counsel, Minnesota Department of Commerce
Representing: Minnesota Department of Commerce

Ann Warner, Manager, Data Engineering, HealthEast
Representing: Health Care Administrators

John Whitington, Chief Information Officer, South Country Health Alliance
Representing: Health Care Purchasers and Employers

Ken Zaiken, Consumer Advocate, AARP Minnesota
Representing: Consumers

Sandy Zutz-Wiczek, Chief Operating Officer, FirstLight Health System
Representing: Community Clinics and FQHCs

Designated Alternates

George Klauser, Executive Director, Altair-ACO, Lutheran Social Services
Alternate Representing: Social Services

Co-Chair: Health Information Exchange Task Force

Paul Kleeberg, MD, Medical Director, Aledade
Alternate Representing: Physicians

Rochelle Olson, MPH, Systems Management Supervisor, Dakota County Public Health
Alternate Representing: Local Public Health

Charles Peterson, President and CEO, The Koble Group
Alternate Representing: Vendors

Mark Sonneborn, Vice President, Information Services, Minnesota Hospital Association
Alternate Representing: Hospitals

Susan Severson, CPEHR, CPHIT, Vice President, Health Information Technology, Stratis Health
Alternate Representing: Quality Improvement

Appendix B: Opioid and e-Heath Report: Summary of the 2017 Minnesota e-Health Advisory Committee's Opioids and e-Health Recommendations

Introduction

In response to the opioid epidemic, Governor Dayton requested the Minnesota e-Health Advisory Committee provide a set of recommendations for using e-health to prevent and respond to opioid misuse and overdose. The advisory committee, with input from the Opioids and e-Health Steering Team and Minnesota Department of Health, Office of Health Information Technology (OHIT), developed seven recommendations. The advisory committee believes implementation of the recommendations can have a significant impact on mitigating the opioid epidemic. OHIT developed this report to summarize the approach, recommendations and next steps of the advisory committee's work on opioids and e-health.

Approach

The approach initially focused on the collection, use, and sharing of information necessary for the electronic prescribing of controlled substances (Figure 1) as requested by the advisory committee. With the request from Governor Dayton and input from the community, the scope was broadened to include additional uses of e-health to prevent and respond to opioid misuse and overdose. The following activities were critical to the development of the recommendations and building greater understanding of using e-health to prevent and respond to the opioid epidemic.

Minnesota Environmental Scan

Prescribers, payers, pharmacies and state agencies provided information and perspectives regarding the electronic health care information needed to address the opioid epidemic. The interviews focused on two areas including:

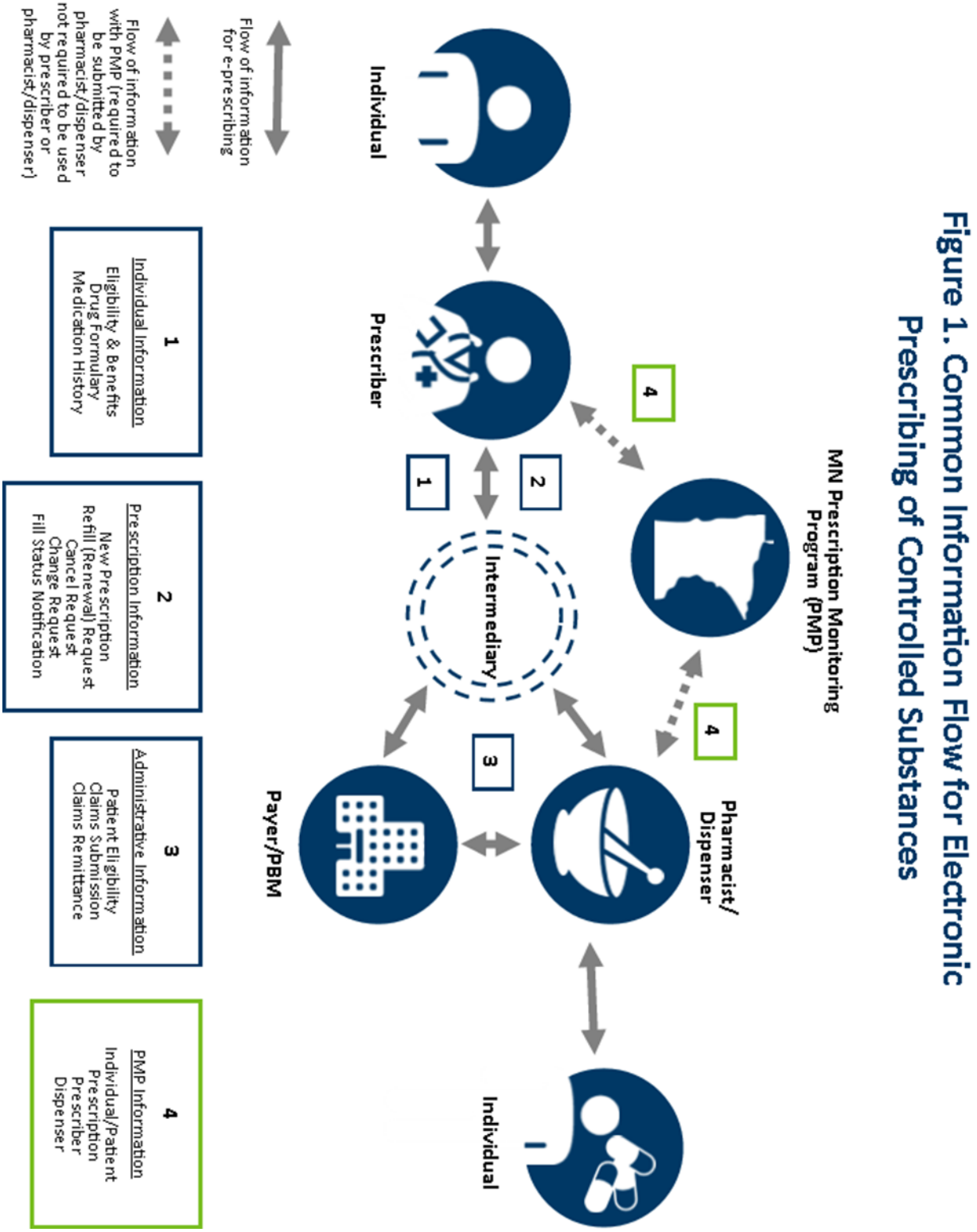
1. Whether and how such information is or could be exchanged via the types of data exchange subject to MN 62J.536 and 62J.495-4982; and
2. Any possible issues or constraints associated with the standard, electronic exchange or use of information needed to address the epidemic and how they might be addressed.

Engaging Partners and Collecting Input during the Minnesota e-Health Summit

During the 2017 Minnesota e-Health Summit's, 'Leveraging e-Health to Prevent and Respond to Opioid Misuse and Overdose' session approximately 30 participants from across the care continuum shared feedback on:

- Preferred/recommended data sources;
- How information can best be provided/communicated via standard, electronic health business transactions and electronic health records;
- How electronic health data can be leveraged to help address the opioid epidemic;
- Key obstacles/challenges to providing/communicating the needed information; and
- Changes/solutions needed to address the challenges/obstacles.

Figure 1. Common Information Flow for Electronic Prescribing of Controlled Substances



Nationwide Scan of Strategies Implemented by States to Address Opioid Epidemic

The scan obtained information about other states' legislative and policy strategies for addressing the epidemic. Key words used in the review included: "opioids," "EPCS" (electronic prescribing of controlled substances), "prescription monitoring program/prescription drug monitoring program," (PMP/PDMP) "medical cannabis," and "individual/patient education."

Opioids and e-Health Steering Team

The Opioids and e-Health Steering Team provided input to the Advisory Committee on recommendations and strategies for using e-health to prevent and respond to opioid misuse and overdose. The participants of the Steering Team included experts in prescribing and dispensing controlled substances, e-prescribing controlled substances, and the Minnesota Prescription Monitoring Program. The Steering Team met twice and shared their perspectives and experiences during numerous advisory committee and public meetings.

Recommendations

The advisory committee believes implementation of the following recommendations can have a significant impact on mitigating the opioid epidemic.

The advisory committee recommends that:

1. By July 2018, the Minnesota Legislature should provide resources to fully implement and ensure compliance with Minnesota Statutes Section 62J.497 including a focus on increasing the rate of e-prescribing of controlled substances from approximately 20 percent (Surescripts 2016 National Progress Report) to over 80 percent by 2020. Implementation of this recommendation should occur with input from the Minnesota e-Health Advisory Committee to:
    a. Provide or ensure statewide education and technical assistance on electronic prescribing (e-prescribing) of controlled substances.
    b. Support full-implementation of all e-prescribing related transactions in the nationally recognized National Council for Prescription Drug Programs Standards (NCPDP), including electronic prior authorization and Formulary and Benefits.
    c. Provide grants to increase the rate of e-prescribing of controlled substances. Grantees include, but are not limited to, prescribers that serve rural or underserved populations; prescribers that have small, independent practices; and other providers needing support such as dentists.
    d. Support the use of evidence-based clinical guidelines and clinical decision support.
    e. Monitor the status of e-prescribing, specifically for controlled substances, and assess the barriers to e-prescribing of controlled substances.
    f. Develop and implement policy options including rulemaking and enforcement for non-compliance of e-prescribing as needed, if goals are not met.

2. By January 2019, the Minnesota Board of Pharmacy, with input from the Minnesota e-Health Advisory Committee, health and health care provider associations, and other stakeholders, should develop requirements and an implementation plan to improve the Prescription

Monitoring Program (PMP). The requirements and implementation plan should include use cases and policies for the required use of the PMP. The implementation plan should:

a. Address affordable, effective and seamless use of the PMP by prescribers and dispensers through the EHR, other HIT, and integration into Minnesota's HIE and include full implementation of clinical guidelines and clinical decision support and access to other states' PMP information.
b. Improve stakeholder input and oversight, representative governance, regulatory authority, and funding of the PMP to support alignment with state and federal requirements and standards, improve data quality and usability, support patient consent and privacy, and meet workforce-training needs.

The Governor and Legislature should appropriate funds for the development and implementation of the requirements and implementation plan to improve the PMP.

3. By July 2018, the Minnesota Legislature should amend Minnesota Statutes, Section 152.126 to expand the permitted uses of Prescription Monitoring Program data. The updated language should ensure that state and federal agencies, tribal governments, academia, local public health, payers, and other partners are able to appropriately access and analyze information for improved prevention, response, and care while safeguarding patient privacy in accordance with state and federal law. Transparent processes and principles developed by the Board of Pharmacy with input from the Minnesota e-Health Advisory Committee and other stakeholders should guide access to the Prescription Monitoring Program data. Potential data uses should include, but are not limited to:
    a. Identify geographic areas and populations showing indicators of misuse and abuse to better target resources for prevention, response, and coordinated care, treatment, and services.
    b. Ensure more timely and accurate responses to misuse and overdoses by leveraging other data sources such as overdose, toxicology, and drug seizure reports; medical examiner/coroner data; payer claims; poison control reports; and birth and death records.
    c. Support the development and use of advanced clinical decision support and clinical guidelines to flag suspicious behavior and/or patterns and identify individuals at risk for opioid misuse at the point of care and beyond.
    d. Identify critical needs for training and best practices for prescribers, dispensers and other providers such as emergency medical services and local public health.

    The Governor and Legislature should appropriate funds to support the expanded uses of the Prescription Monitoring Programs data, and develop and implement the transparent processes and principles to guide access to data.

4. State agencies and associations should, by September 2018, review, update, and provide education on e-health and opioids policies and guidelines to ensure dispensers, prescribers, payers, and other providers, including the care team, have appropriate and timely access to health information, can subsequently share information, and understand their scope of action

related to the information. Use cases should include, but are not limited to, instances when prescribing and dispensing practices are outside nationally recognized clinical guidelines, such as those published by the Centers for Disease Control and Prevention and the U.S. Food and Drug Administration, and individuals are at-risk for misuse and abuse.

5. The Governor, by July 2018, should ensure access and coverage for all Minnesotans and providers, and provide resources for grants and technical assistance, to expand access to services and care enabled by telehealth, telemedicine and other forms of virtual technology to fill access gaps in opioid tapering and withdrawal, chemical dependency, mental health, and alternative pain treatment and services.

6. The Governor should support state agencies and stakeholders in participating in statewide coordinated HIE services. The support should be consistent with the findings of Minnesota Health Information Exchange Study, which will be submitted to the Legislature in February of 2018, align with input from the Minnesota e-Health Advisory Committee, ensure providers and public health have access to information to support individual and community health services, and support:
    a. Alerts for emergency services, urgent care, and other medical visits relating to substance misuse and overdose.
    b. Referrals to substance abuse treatment and community services.
    c. Access to patient health history including medication lists.

7. The Minnesota Department of Health, by December 2018, should submit to the Governor and the Legislature an update to their informatics profile that assesses the gaps in current information and information systems used to prevent and respond to substance misuse and overdose and identify resources needed to fill those gaps. The Governor and Legislature should appropriate funds to ensure those needs are met.

The advisory committee also recognized that mitigating the opioid epidemic goes beyond e-health. There is a need for better access to and coverage for health services, specifically opioid tapering and withdrawal, chemical dependency, mental health and alternative pain treatment and services. Therefore, they also recommend the Governor work to ensure all Minnesotans have access to the treatment and services needed to achieve health and wellbeing.

Next Steps

The advisory committee and its stakeholders will continue to prioritize work to mitigate the opioid epidemic. In the coming months, it will move forward with the findings of the legislatively mandated study on HIE, which improves the seamless flow of information to prescribers and dispensers. It will continue to monitor and provide input into state and national activities regarding e-prescribing of controlled substances, Prescription Monitoring Program, and related issues.